

**REMARKS**

This Amendment cancels claims 1-12 and adds new claims 13-21. New claim 13 is supported at page 8, line 3 to page 9, line 24. New claims 14-16 and 18-21 correspond to claims 2-4 and 9-12, respectively. New claim 17 is taken from claim 8. Claims 13-21 are pending.

This Amendment overcomes the 35 U.S.C. § 112, second paragraph, rejection of claims 1-12. These claims have been canceled in favor of new claims 13-21, which do not recite "lignan skeleton" or "L". Reconsideration and withdrawal of the indefiniteness rejection of claims 1-12 are earnestly requested.

The 35 U.S.C. § 102(b) rejection of claims 1, 5-8 and 12 over U.S. Published Application 2005/0169947 to Korte et al. is respectfully traversed. The claimed inclusion complex comprises hydroxymatairesinol, its isomer or its ester (hereinafter collectively referred to as HMR), and a cyclodextrin. Korte et al. fails to specifically disclose the claimed complex. Thus, none of the formulations in Examples 1-8 illustrate an inclusion complex of HMR and a cyclodextrin. Reconsideration and withdrawal of the anticipation rejection of claims 1, 5-8 and 12 over Korte et al. are respectfully requested.

The 35 U.S.C. § 103(a) rejection of claims 1-5, 7 and 9-12 over U.S. Patent 5,180,588 to Shinmen et al., U.S. Patent No. 6,559,168 to Marfat et al. and U.S. Patent No. 6,395,279 to Empie et al., is respectfully traversed. The claimed inclusion complex comprises HMR and a cyclodextrin.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition because these references, taken together, do not disclose or suggest an inclusion complex of HMR and a cyclodextrin. Instead, Shinmen et al. discloses a liver function improver which can be converted into a cyclodextrin inclusion complex. However, Shinmen et al. does not disclose an inclusion complex of HMR and cyclodextrin. Marfat et al., directed to thiazolyl-acid derivatives useful as inhibitors of PDE4 isoenzymes, also mentions lignans as another type of PDE4 inhibitors. However, Marfat et al., like Shinmen et al., fails to disclose an inclusion complex of HMR and cyclodextrin. Empie et al. discloses a composition for treatment of cancer, which composition may contain lignans. However, there is no disclosure of an inclusion complex of HMR and cyclodextrin. One of ordinary skill in the art, having read the cited references, would not be led to the claimed inclusion complex. Reconsideration and

withdrawal of the obviousness rejection of claims 1-5, 7 and 9-12 over Shinmen et al., Marfat et al. and Empie et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 1-4, 6, 7 and 9-12 over U.S. Patent No. 6,413,533 to Steiner et al., Marfat et al., and Empie et al. is respectfully traversed. As discussed above, the claimed inclusion complex comprises HMR and a cyclodextrin.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition because these references, taken together, do not disclose or suggest an inclusion complex of HMR and a cyclodextrin. The deficiencies of Marfat et al. and Empie et al., discussed above, are not remedied by the additional disclosure of Steiner et al. Instead, Steiner et al. relates to a method of suppressing or inhibiting latent prostate cancer by using a pharmaceutical composition comprising an antiestrogen, such as a lignan, which may be complexed with a cyclodextrin. Importantly, Steiner et al. does not disclose or suggest an inclusion complex of HMR and a cyclodextrin. Reconsideration and withdrawal of the obviousness rejection of claims 1-4, 6, 7 and 9-12 over Steiner et al., Marfat et al. and Empie et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 1-8 over Korte et al. in view of Marfat et al. and Empie et al. is respectfully traversed. As discussed above, the claimed inclusion complex comprises HMR and a cyclodextrin.

The cited combination of references does not disclose or suggest the claimed composition. As discussed above, none of the Korte et al. formulations comprise an inclusion complex of HMR and a cyclodextrin. Similarly, Marfat et al. and Empie et al. also fail to disclose or suggest the claimed inclusion complex. Reconsideration and withdrawal of the obviousness rejection of claims 1-8 over Korte et al. in view of Marfat et al. and Empie et al. are requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 1-12, and issuance of a Notice of Allowance directed to claims 13-21, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

It is not believed any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is

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AMENDMENT

**PATENT**

authorized to charge our Deposit Account No. 50-1258 in the amount  
of any such required fee.

Respectfully submitted,

/James C. Lydon/

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